By: Toth, Burrows, Harris of Anderson, Bonnen H.B. No. 638

Substitute the following for H.B. No. 638:

By: Klick C.S.H.B. No. 638

A BILL TO BE ENTITLED

AN ACT

relating to access to certain investigational drugs, biological products, and devices used in clinical trials by patients with severe chronic diseases.

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:

SECTION 1. (a) This Act shall be known as Mary Lou's Law.

(b) The legislature finds that:

(1) the Right To Try Act, as added by Chapter 502 (H.B. 21), Acts of the 84th Legislature, Regular Session, 2015, has had tremendous success in saving the lives of many patients with a terminal illness;

(2) the process for approving the use of investigational drugs, biological products, and devices by patients without a terminal illness who need access to the drugs, products, or devices takes many years in the United States;

(3) patients who are battling a severe chronic disease that is debilitating or causes severe pain do not have the luxury of waiting until the United States Food and Drug Administration gives final approval for an investigational drug, biological product, or device;

(4) the United States Food and Drug Administration standards for the use of investigational drugs, biological products, and devices may deny the benefits of potentially life-altering treatment to patients with a severe chronic disease;

(5) patients with a severe chronic disease have a fundamental right to pursue the preservation of their state of life by accessing available investigational drugs, biological products, and devices;

(6) the use of available investigational drugs, biological products, and devices is a decision that a patient with a severe chronic disease should make in consultation with the patient's physician and is not a decision the government should make; and

(7) the decision to use an investigational drug, biological product, or device should be made with full awareness of the potential risks, benefits, and consequences to a patient with a severe chronic disease and the patient's family.

(c) It is the intent of the legislature to allow patients with a severe chronic disease to use potentially life-altering investigational drugs, biological products, and devices.

SECTION 2. Subtitle C, Title 6, Health and Safety Code, is amended by adding Chapter 490 to read as follows:

CHAPTER 490. ACCESS TO INVESTIGATIONAL TREATMENTS FOR PATIENTS WITH SEVERE CHRONIC DISEASES

SUBCHAPTER A. GENERAL PROVISIONS

Sec. 490.001. DEFINITIONS. In this chapter:

(1) "Commissioner" means the commissioner of state health services.

(2) "Executive commissioner" means the executive commissioner of the Health and Human Services Commission.

(3) "Investigational drug, biological product, or

device" means a drug, biological product, or device that has successfully completed phase one of a clinical trial but has not yet been approved for general use by the United States Food and Drug Administration or its international equivalent and that remains under investigation in the clinical trial. The term does not include low-THC cannabis, as defined by Section 169.001, Occupations Code, or a product containing marihuana, as defined by Section 481.002, regardless of whether the cannabis or product successfully completed phase one of a clinical trial.

(4) "Severe chronic disease" means a condition, injury, or illness that:

(A) may be treated;

(B) may not be cured or eliminated; and

(C) entails significant functional impairment or severe pain.

Sec. 490.002. DESIGNATION OF SEVERE CHRONIC DISEASES. The commissioner shall designate the medical conditions considered to be severe chronic diseases under this chapter.

Sec. 490.003. RULES. The executive commissioner shall adopt rules necessary to administer this chapter.

SUBCHAPTER B. ACCESS TO INVESTIGATIONAL DRUGS, BIOLOGICAL PRODUCTS, AND DEVICES FOR PATIENTS WITH SEVERE CHRONIC DISEASES

Sec. 490.051. PATIENT ELIGIBILITY. A patient is eligible to access and use an investigational drug, biological product, or device under this chapter if:

(1) the patient has a severe chronic disease the commissioner designates under Section 490.002 that the patient's

treating physician confirms in writing;

(2) the use of the investigational drug, biological product, or device is consistent with this chapter and rules adopted under this chapter; and

(3) the patient's physician:

(A) in consultation with the patient, considers all other treatment options the United States Food and Drug Administration has currently approved and determines those treatment options are unavailable or unlikely to provide relief for the significant impairment or severe pain associated with the patient's severe chronic disease; and

(B) recommends or prescribes in writing the patient's use of a specific class of investigational drug, biological product, or device.

Sec. 490.052. INFORMED CONSENT. (a) A physician may recommend or prescribe an investigational drug, biological product, or device, only to an eligible patient who signs a written informed consent. If the patient is a minor or lacks the mental capacity to provide informed consent, a parent, guardian, or conservator may provide informed consent on the patient's behalf.

(b) The commissioner may prescribe a form for the informed consent required under this section.

Sec. 490.053. CAUSE OF ACTION NOT CREATED. This chapter does not create a private or state cause of action against a manufacturer of an investigational drug, biological product, or device or against any other person or entity involved in the care of an eligible patient using the investigational drug, biological

product, or device for any harm to the patient resulting from the investigational drug, biological product, or device.

Sec. 490.054. STATE MAY NOT INTERFERE WITH ACCESS TO INVESTIGATIONAL DRUG, BIOLOGICAL PRODUCT, OR DEVICE. An official, employee, or agent of this state may not prevent or attempt to prevent an eligible patient's access to an investigational drug, biological product, or device under this chapter unless the drug, biological product, or device is considered adulterated or misbranded under Chapter 431. For purposes of this section, a governmental entity may not consider the drug, biological product, or device to be adulterated or misbranded based solely on the United States Food and Drug Administration not yet finally approving the drug, biological product, or device.

SUBCHAPTER C. HEALTH INSURANCE

Sec. 490.101. EFFECT ON HEALTH CARE COVERAGE FOR CLINICAL TRIAL ENROLLEES. This chapter does not affect the coverage of enrollees in clinical trials under Chapter 1379, Insurance Code.

SUBCHAPTER D. PHYSICIANS

Sec. 490.151. ACTION AGAINST PHYSICIAN'S LICENSE PROHIBITED. Notwithstanding any other law, the Texas Medical Board may not revoke, fail to renew, suspend, or take any action against a physician's license under Subchapter B, Chapter 164, Occupations Code, based solely on the physician's recommendations to an eligible patient regarding access to or treatment with an investigational drug, biological product, or device, provided that the recommendations meet the requirements of this chapter and rules adopted under this chapter.

SECTION 3. (a) As soon as practicable after the effective date of this Act, the commissioner of state health services shall designate the medical conditions considered to be severe chronic diseases as required by Section 490.002, Health and Safety Code, as added by this Act.

(b) As soon as practicable after the effective date of this Act, the executive commissioner of the Health and Human Services Commission shall adopt the rules required by Section 490.003, Health and Safety Code, as added by this Act. The executive commissioner may adopt initial rules in the manner provided by law for emergency rules.

SECTION 4. This Act takes effect immediately if it receives a vote of two-thirds of all the members elected to each house, as provided by Section 39, Article III, Texas Constitution. If this Act does not receive the vote necessary for immediate effect, this Act takes effect September 1, 2023.